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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,095	03/18/2004	Nasrin Mesaeli	81190-2602	1202

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Michael R. Williams
Ade & Company
1700-360 Main Street
Winnipeg, MB R3C 3Z3
CANADA

EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,095	MESAELI, NASRIN	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Application, filed March 18, 2004, claims priority to U.S. Provisional Application, 60/455,399, filed March 18, 2003.

Claims 1-11 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a transgenic mouse and method of making a transgenic mouse whose genome comprises a transgene comprising a transcriptional control region operably linked to cDNA encoding calreticulin (CRT) wherein said control region comprises a promoter wherein expression of CRT in the vascular smooth muscle cells results in hemangioma formation, classified in class 800, subclass 18.

II. Claim 6, drawn to a method for screening compounds that inhibit vascular tumor formation in a transgenic mouse, classified in class 800, subclass 3, or classified in class 424, subclass 9.1+.

III. Claim 7, drawn to a compound isolated from a method of screening compounds that inhibit vascular tumor formation, classified in class 514, subclass 1+.

IV. Claim 8, drawn to a method of testing the therapeutic activity of a pharmacological agent on Kaposiform hemangioenothelioma, classified in class 800, subclass 3 or class 424, subclass 9.1+.

V. Claim 9, drawn to a compound isolated from a method of testing the therapeutic activity of a pharmacological agent on Kaposiform hemangioenothelioma, classified in class 514, subclass 1+.

VI. Claim 10, drawn to a method of inhibiting hemangioma formation comprising administering an effective amount of a matrix metalloproteinase inhibitor, classified in class 514, subclass 1+.

VII. Claim 11, drawn to a method of inhibiting hemangioma comprising administering an effective amount of virally-administered small interference RNA (siRNA) corresponding to a portion of CRT mRNA, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, Invention II is to a method for screening compounds that inhibit vascular tumor formation in a transgenic mouse. Invention III is to a compound isolated from a method of screening compounds that inhibit vascular tumor formation. In addition to being able to isolate chemical compounds, Invention II can be used to isolate genes that inhibit vascular tumor formation.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case Invention IV is to a method of testing the therapeutic activity of a pharmacological agent on Kaposiform hemangioenothelioma. Invention V is to a compound isolated from a method of testing the therapeutic activity of a pharmacological agent on Kaposiform hemangioenothelioma. In addition to being able to isolate chemical compounds, Invention IV can be used to isolate genes that can be tested for therapeutic activity.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, while Inventions VI and VII are to a method of inhibiting hemangioma, Invention VI is to a method comprising administering an effective amount of a metalloproteinase inhibitor and Invention VII is to a method comprising administering an effective amount of virally-administered small interference RNA (siRNA) corresponding to a portion of CRT mRNA. Invention VI does not depend on Invention VII to function and vice versa.

Inventions I and II/III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention I is to a transgenic mouse and method of making a transgenic mouse whose genome comprises a transgene comprising a transcriptional control region operably linked to cDNA encoding calreticulin (CRT) wherein said control region comprises a promoter wherein expression of CRT in the vascular smooth muscle cells results in hemangioma formation. Invention II/III is to a method for screening compounds that inhibit vascular tumor formation in a transgenic mouse and to a compound isolated from the screening method. Invention I can be used in other methods, such as in a method for testing the therapeutic activity of a pharmacological agent on Kaposiform hemangioenothelioma.

Inventions I and IV/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention I is to a transgenic mouse and method of making a transgenic mouse whose genome comprises a transgene comprising a transcriptional control region operably linked to cDNA encoding calreticulin (CRT) wherein said control region comprises a promoter wherein expression of CRT in the vascular smooth muscle cells results in hemangioma formation. Invention IV/V is to a method of testing the therapeutic activity of a pharmacological agent on Kaposiform hemangioenothelioma and to a compound

isolated from the testing method. Invention I can be used in other methods, such as in screening compounds that inhibit vascular tumor formation.

Inventions I and VI/VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is to a transgenic mouse and method of making a transgenic mouse whose genome comprises a transgene comprising a transcriptional control region operably linked to cDNA encoding calreticulin (CRT) wherein said control region comprises a promoter wherein expression of CRT in the vascular smooth muscle cells results in hemangioma formation. Invention VI/VII are to methods of inhibiting hemangioma. Invention I does not depend on Invention VI/VII to function and vice versa.

Inventions II/III and IV/V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention II/III are to a method for screening compounds that inhibit vascular tumor formation in a transgenic mouse and to a compound isolated from a method of screening. Invention IV/V is to a method of testing the therapeutic activity of a pharmacological agent on Kaposiform hemangioenothelioma and to a compound isolated from the testing method. Invention II/III does not depend on Invention IV/V to function and vice versa.

Inventions II/III and VI/VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention II/III is to a method for screening compounds that inhibit vascular tumor formation in a transgenic mouse and to a compound isolated frm a method of screening. Invention VI/VII are to methods of inhibiting hemangioma. Invention II does not depend on Invention VI/VII to function and vice versa.

Inventions IV/V and VI/VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions IV/V are to a method of testing the therapeutic activity of a pharmacological agent on Kaposiform hemangioenothelioma and the compound isolated from the testing method. Inventions VI/VII are to methods of inhibiting hemangioma. Inventions IV/V do not depend on Inventions VI/VII to function and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and the search for one Group is not required for another, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

Joe Woitach
AU1637